AUG 1 8 2000

K002415

SUMMARY OF SAFETY AND EFFECTIVENESS

(As required by 21 CFR 807.92)

1. General Information

Classification:	Class II Magnetic Resonance Imaging (MRI) System
Common/Usual Name:	Magnetic Resonance Imaging (MRI) Option
Proprietary Name:	PowerDrive 350 Option
Establishment Registration:	Marconi Medical Systems, Inc. World Headquarters 595 Miner Road Highland Heights, Ohio 44143 Contact: Duane Praschan Phone: (440) 483-3000 FDA Owner Number: #1580240 FDA Registration Number: #1525965
Performance Standards:	No applicable performance standards have been issued under section 514 of the Food, Drug and Cosmetic Act.

2. Intended Uses

The PowerDrive 350 Option does not change the existing indications for the Eclipse and Polaris systems as defined below.

The Marconi Medical Systems Eclipse and Polaris systems are indicated for use as a NMR device that produces images that: (1) correspond to the distribution of protons exhibiting NMR, (2) depend upon the NMR parameters (proton density, flow velocity, spin-lattice relaxation time (T1), and spin-spin relaxation time (T2)) and (3) display the soft tissue structure of the head and whole body. When interpreted by a trained physician, these images yield information that can be useful in the determination of a diagnosis.

3. Device Description

The Marconi PowerDrive 350 Option consists of new high performance gradient amplifiers, modified standard sequences and increased operating limits for time varying magnetic fields. This option does not change the fundamental scientific technology of the Eclipse and Polaris magnetic resonance imaging systems.

4. Safety and Effectiveness

The Marconi PowerDrive 350 Option for Eclipse and Polaris systems is similar in technological characteristics and intended use to the standard configurations for these systems. The following table has been created to demonstrate their substantial equivalence.

Substantial Equivalence Chart

Parameter	**PowerDrive 350 Option for Eclipse/Polaris Systems**	**Predicate Device: Eclipse/Polaris Systems (K964626)**
Gradient Coils	Same.	Water-cooled self-shielded gradient system for all performance levels.
Max. Gradient Strength	30 mT/m	16, 20 or 27 mT/m
Max. Slew Rate	120 mT/m/msec	25, 40, 72 mT/m/msec
Gradient Amplifiers	270 A RMS, 440 A peak, 1200 V	150 A RMS, 300 A peak, 400 V or 270 A RMS, 440 A peak, 600 V
Standard Imaging Sequences	Same.	Standard imaging sequences with image resolution, inter-echo spacing, echo times and motion artifact suppression limited to gradient power output of system.
Time Varying Magnetic Field	All gradient performance levels: Normal Operating Mode: $dB/dt \leq 40$ T/s First Controlled Operating Mode: $40 \text{ T/s} < dB/dt \leq 80$ T/s	All gradient performance levels: Normal Operating Mode: $dB/dt \leq 40$ T/s First Controlled Operating Mode: $40 \text{ T/s} < dB/dt \leq 60$ T/s
Acoustic Noise Typical Worst Case	 94.5 dBA (average) 107.3 dB (peak) 114.7 dBA (average) 123.2 dB (peak)	 80.6 dBA (average) 93.3 dB (peak) 115.1 dBA (average) 123.8 dB (peak)

Parameter	PowerDrive 350 Option for Eclipse/Polaris Systems	Predicate Device: Eclipse/Polaris Systems (K964626)
Intended Use / Indications for Use	Same.	The Eclipse and Polaris systems are indicated for use as a NMR device that produces images that: (1) correspond to the distribution of protons exhibiting NMR, (2) depend upon the NMR parameters (proton density, flow velocity, spin-lattice relaxation time (T1), and spin-spin relaxation time (T2)) and (3) display the soft tissue structure of the head and whole body. When interpreted by a trained physician, these images yield information that can be useful in the determination of a diagnosis.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 8 2000

Duane Prachan
Manager, Regulatory Affairs
Marconi Medical Systems, Inc.
595 Miner Road
Cleveland, OH 44143

Re: K002415
PowerDrive 350 Option
Dated: August 4, 2000
Received: August 8, 2000
Regulatory class: II
21 CFR 892.1000/Procode: 90 LNH

Dear Mr. Prachan:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

510(k) Number (if known): K00 2415

Device Name: PowerDrive 350 Option

Indications for Use:

The Marconi Medical Systems Eclipse and Polaris systems are indicated for use as a NMR device that produces images that: (1) correspond to the distribution of protons exhibiting NMR, (2) depend upon the NMR parameters (proton density, flow velocity, spin-lattice relaxation time (T1), and spin-spin relaxation time (T2)) and (3) display the soft tissue structure of the head and whole body. When interpreted by a trained physician, these images yield information that can be useful in the determination of a diagnosis.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K002415

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)